



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

January 5, 2006

NOTE TO DOCKET NO. 2004N-0556

SUBJECT: Obstetrical and Gynecological Devices; Designation of Special Control for Condom and Condom with Spermicidal Lubricant; Proposed Rule

PUBLICATION DATE: November 14, 2005

On September 30, 1993, President Clinton signed Executive Order 12866--Regulatory Planning and Review. This Executive Order sets forth the Administration's principles and requirements for the Federal regulatory process. Under section 6 (a) (3) (E) of the Executive Order, for "significant regulatory actions," Federal agencies must make certain information available to the public after publication of the regulatory action in the Federal Register.

Pursuant to Executive Order 12866, FDA has attached, for significant regulatory actions, in this docket the following information:

- 1) A copy of the draft regulatory action as submitted to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) for review, including any materials or assessments, required by the Executive Order that accompanied the draft (Tab A);
- 2) The substantive changes between the draft submitted to OIRA for review and the action subsequently announced, including those changes in the regulatory action that were made at the suggestion or recommendation of OIRA (Tab B).

Nancy E. Pirt
Regulations, Policy
and Management Staff (HF-26)

Attachments

2004N-0556

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